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Educational interventions to improve self-care and reduce self-neglect in Iranian elderly people with diabetes

Submission date
24/09/2021

Recruitment status
No longer recruiting

Registration date
28/09/2021

Overall study status
Completed

Last Edited
17/06/2024

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Due to the increase in life expectancy, management of diabetes is very important and older diabetics should be able to take care of themselves to prevent or delay the complications of diabetes. The self-care deficit in elderly people with diabetes is due to an irreversible decrease in physical and cognitive function, and elderly people with diabetes have more cognitive problems than healthy individuals due to defects in memory and executive function. Mindfulness interventions can help change erroneous thoughts and behaviour patterns and a self-regulatory approach can empower the elderly in a step-by-step manner. The impact of mindfulness interventions or self-regulatory interventions has been examined separately but the effect of a combination of mindful self-care and self-regulation interventions has not been examined until now. The aim of this study is to compare the effect of self-regulatory intervention programs only with a combination of mindful self-care and self-regulation interventions on self-care, self-regulation, mindful self-care, and self-neglect in elderly people with diabetes.

Who can participate?
Community-dwelling elderly people aged 60-80 years with diabetes

What does the study involve?
First, participants are selected from three centers that are randomly selected by simple random sampling. Each center is assigned to one intervention group and the number of participants in each center is 45. Seniors fill out five questionnaires, and then the daily training starts via WhatsApp and lasts for 2 months. After 4 weeks testing is performed and after 16 weeks a follow-up is performed.

What are the possible benefits and risks of participating?
Interventions improve self-care in the elderly and are not harmful.

Where is the study run from?
Shiraz University of Medical Sciences (Iran)

When is the study starting and how long is it expected to run for?
February 2020 to July 2021

Who is funding the study?
Shiraz University of Medical Sciences (Iran)

Who is the main contact?
1. Dr Mohammad Hossein Kaveh, mhkaveh255@gmail.com
2. Mohadeseh Motamed-Jahromi, mohadesehmotamed@gmail.com

Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
19030

Study information

Scientific Title
Designing and evaluating educational interventions based on mindfulness and/or self-regulation in improving self-neglect and self-care in elderly people with diabetes in Shiraz

Study objectives
Do educational interventions based on mindfulness or self-regulation affect the improvement of self-neglect and self-care of the elderly with diabetes in Shiraz, Iran?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/02/2020, Shiraz University of Medical Sciences Research Ethics Committee (Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran; +98 (0)21 81455618; ethics@behdasht.gov.ir), ref: IR.SUMS.REC.1398.1365

Study design
Three-arm cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Community-dwelling elderly people with diabetes

Interventions
This study was conducted over 24 weeks at three Urban Health Centers in Shiraz, Iran. Among the urban health centers with the most people with diabetes, three centers were randomly selected and then the centers were randomly assigned to the intervention and control groups. The elderly who were eligible were identified and 45 people in each center were selected using a list of random numbers.

Due to the prevalence of COVID-19, the training was done through WhatsApp software. Three WhatsApp groups were formed to provide training to the participants. In all three groups, training content was sent daily to participants for the first 2 months, and for the next 4 months training continued only on Mondays. Messages were sent in the form of text, images, media, audio, images, emoticons, and links. Data were collected between December 2020 and May 2021. In the first arm, a self-care training program focused on behavior change based on self-

regulatory theory was sent. In the second arm, a combined intervention was presented that included mindful self-care training and a self-care training program based on self-regulatory theory. In the control arm (CO), COVID-19 prevention training was sent to the participants. Five questionnaires including demographic information, summary of diabetes self-care activities (SDSCA), the mindful self-care questionnaire (MSCS), Elder Self-Neglect Scale (ESNS), and Short form Self-Regulation Questionnaire (SSRQ) were used. Information from telephone interviews was collected at baseline, week 4, and week 16 after the intervention programs.

Intervention Type
Behavioural

Primary outcome(s)
Measured at baseline, week 4, and week 16 after intervention programs:
1. Demographic information collected using a researcher-made questionnaire that included gender, age, marital status, education level, occupational status, living arrangement, duration of diabetes, other diseases
2. The different activities of diabetic patients during the previous 7 days measured by a 12-item self-report scale: Summary of Diabetes Self-Care Activities (SDSCA)
3. Mindful self-care assessed using the mindful self-care scale (MSCS). This instrument measures the frequency of behavior within the past week in six subscales: mindful relaxation, physical care, self-compassion, and purpose, supportive relationships, supportive structure, mindful awareness, and three general items
4. Elder self-neglect measured by the Elder Self-Neglect Scale (ESNS) developed by the researchers. It consists of 26 items that specified the frequency of the self-neglect behaviors.
5. Self-regulation behavior in elder diabetics measured by the Short form Self-Regulation Questionnaire (SSRQ). It included 31 items that the higher the scores indicate a better level of self-regulation

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/07/2021

Eligibility

Key inclusion criteria
1. Age 60-80 years old
2. Type 2 diabetes (duration ≥6 months)
3. Sufficient ability to read and write
4. Sufficient activity daily living
5. Sufficient WhatsApp and Internet literacy
6. Smartphone and Internet access

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Senior

Sex
All

Key exclusion criteria
1. Persistent serious psychological problem
2. Does not answer phone calls and messages more than three times
3. Reluctant to participate in the intervention

Date of first enrolment
15/11/2020

Date of final enrolment
15/07/2021

Locations

Countries of recruitment
Iran

Study participating centre
Pardis Urbon Health Center
Fars Province, Bahonar Underpass
Shiraz
Iran
71 9100 2030

Study participating centre
Vali-e-Asr Health Center
Fars Province, Sharak-e-Shahid Dr.Bahonar, Shah Gholi Beigi
Shiraz
Iran
71 3824 5884

Study participating centre
Ghotb Al Din Health Center
Fars Province, Fakhr Abad St
Shiraz
Iran
71 3821 9638

Sponsor information

Organisation
Shiraz University of Medical Sciences

ROR
https://ror.org/01n3s4692

Funder(s)

Funder type
University/education

Funder Name
Shiraz University of Medical Sciences

Alternative Name(s)
SUMS

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Iran

Results and Publications

Individual participant data (IPD) sharing plan
SPSS datasets without participants' names will send to academic readers after publishing the relevant articles if requested from Mohadeseh Motamed-Jahromi (mohadesehmotamed@gmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/06/2024	17/06/2024	Yes	No